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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/964,161	09/26/2001	John Clifford Head	CELL-0145	9582

7590 11/17/2004
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EXAMINER

TRUONG, TAMTHOM NGO

ART UNIT PAPER NUMBER

1624

DATE MAILED: 11/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/964,161

Applicant(s)

HEAD ET AL.

Examiner

Tamthom N. Truong

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-6,8-11 and 14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1, 4-6, 8-11 and 14 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendment of 08-05-04 has been considered. Although amended claims have overcome the previous rejections of 112/2nd, and 102(b) based on WO 97/31907, said claims recite many different ring systems for R¹ and Het, and thus prompt the following restriction.

Claims 2-3, 7, 12 and 13 have been cancelled. Claims 1, 4-6, 8-11 and 14 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

1. Claims 1, 4-6, 8-11, and 14, drawn to compounds of formula (I) (or Ia) having the following substituents:

R¹ is phenyl (or W is -CH= in formula Ia);

Het is benzofuryl, [2,3-dihydro]-benzofuryl, benzopyranyl, or [3,4-dihydro]-benzopyranyl;

And pharmaceutical composition thereof,

classified in classes 514 and 549, various subclasses depending on substituents.

2. Claims 1, 4-6, 8-11, and 14, drawn to compounds of formula (I) (or Ia) having the following substituents:

R¹ is phenyl (or W is -CH= in formula Ia);

Het is benzothienyl;

And pharmaceutical composition thereof,

classified in classes 514 and 549, various subclasses.

3. Claims 1, 4-6, 8-11, and 14, drawn to compounds of formula (I) (or Ia) having the following substituents:

R¹ is phenyl (or W is -CH= in formula Ia);

Het is benzotriazolyl;

And pharmaceutical composition thereof,

classified in classes 514 and 548, various subclasses depending on substituents.

4. Claims 1, 4-6, 8-11, and 14, drawn to compounds of formula (I) (or Ia) having the following substituents:

R¹ is phenyl (or W is -CH= in formula Ia);

Het is indolyl or isoindolyl;

And pharmaceutical composition thereof,

classified in classes 514 and 548, various subclasses.

5. Claims 1, 4-6, 8-11, and 14, drawn to compounds of formula (I) (or Ia) having the following substituents:

R¹ is phenyl (or W is -CH= in formula Ia);

Het is benzimidazolyl or imidazolyl[1,2-a]pyridyl;

And pharmaceutical composition thereof,

classified in classes 514 and 548, various subclasses depending on substituents.

6. Claims 1, 4-6, 8-11, and 14, drawn to compounds of formula (I) (or Ia) having the following substituents:

R¹ is phenyl (or W is –CH= in formula Ia);

Het is benzothiazolyl;

And pharmaceutical composition thereof,

classified in classes 514 and 548, various subclasses.

7. Claims 1, 4-6, 8-11, and 14, drawn to compounds of formula (I) (or Ia) having the following substituents:

R¹ is phenyl (or W is –CH= in formula Ia);

Het is benzoxazolyl;

And pharmaceutical composition thereof,

classified in classes 514 and 548, various subclasses.

8. Claims 1, 4-6, 8-11, and 14, drawn to compounds of formula (I) (or Ia) having the following substituents:

R¹ is phenyl (or W is –CH= in formula Ia);

Het is quinolinyl, naphthyridinyl, pyrido[3,4-b]pyridyl, pyrido[3,2-b]pyridyl, pyrido[4,3-b]pyridyl, isoquinolinyl, 5,6,7,8-tetrahydroisoquinolinyl, or 5,6,7,8-tetrahydroquinolinyl;

And pharmaceutical composition thereof,

classified in classes 514 and 546, various subclasses.

9. Claims 1, 4-6, 8-11, and 14, drawn to compounds of formula (I) (or Ia) having the following substituents:

R¹ is phenyl (or W is –CH= in formula Ia);

Het is quinazolyl;

And pharmaceutical composition thereof,

classified in classes 514 and 544, various subclasses.

10. Claims 1, 4-6, 8-11, and 14, drawn to compounds of formula (I) (or Ia) having the following substituents:

R¹ is phenyl (or W is -CH= in formula Ia);

Het is tetrazolyl;

And pharmaceutical composition thereof,

classified in classes 514 and 548, various subclasses.

11. Claims 1, 4-6, 8-11, and 14, drawn to compounds of formula (I) (or Ia) having the following substituents:

R¹ is phenyl (or W is -CH= in formula Ia);

Het is imidyl;

And pharmaceutical composition thereof,

classified in classes 514 and 560, various subclasses.

12. Claims 1, 4-6, 8-11, and 14, drawn to compounds of formula (I) (or Ia) having the following substituents:

R¹ is pyridyl (or W is -N= in formula Ia);

Het is a bicyclic system (recited in claim 1) that is **not** quinazoliny;

And pharmaceutical composition thereof,

classified in classes 514, 546, 548, and 549, various subclasses.

13. Claims 1, 4-6, 8-10, and 14, drawn to compounds of formula (I) (or Ia) having the following substituents:

R¹ is pyridyl (or W is -N= in formula Ia);

Het is quinazolinyl;

And pharmaceutical composition thereof,

classified in classes 514, 546, 548, and 549, various subclasses.

14. Claims 1, 4-6, 8-11, and 14, drawn to compounds of formula (I) having the following substituents:

R¹ is pyrimidyl;

Het is a bicyclic system (recited in claim 1) that is **not** quinazolinyl;

And pharmaceutical composition thereof,

classified in classes 514 and 544, various subclasses.

15. Claims 1, 4-6, 8-11, and 14, drawn to compounds of formula (I) having the following substituents:

R¹ is pyrimidyl;

Het is quinazolinyl;

And pharmaceutical composition thereof,

classified in classes 514 and 544, various subclasses.

16. Claims 1, 4-6, 8-11, and 14, drawn to compounds of formula (I) having the following substituents:

R¹ is **not** phenyl, pyridyl, or pyrimidyl;

Het is any ring defined in claim 1;

And pharmaceutical composition thereof,

classified in classes 514, 544, 546, 548 and 549 various subclasses. Further restriction or election of species will be required if this group is elected.

The inventions are distinct, each from the other because of the following reasons:

- a. Inventions of groups 1-16 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are defined by various rings or ring systems represented by R^1 and Het.
- b. Depending on the combination of R^1 and Het, compounds of formula I or Ia will have physical, chemical and biological properties that are distinct over each other. Therefore, a reference that anticipated or rendered obvious the compound of one group would not do so to those of other groups. Thus, a separate search is required for each group which poses a burden of searching.
- c. A preliminary search in EAST for all involved classes and subclasses yields a total of more than 10,000 hits. This is evident of a serious burden of searching.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art due to their recognized divergent subject matter, and to search the 16

groups of distinct inventions would indeed impose a serious burden upon the examiner in charge of this invention, restriction for examination purposes as indicated is proper.


Due to the complexity of the grouping, the restriction is presented in writing.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

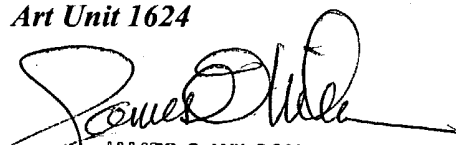
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 703-305-4485. The examiner can normally be reached on M-F (9:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Tamthom N. Truong
Examiner
Art Unit 1624

11-10-04


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